

**AFFIDAVIT OF SPECIAL AGENT PAUL S. BAUMRIND,
FEDERAL BUREAU OF INVESTIGATION,
IN SUPPORT OF A CRIMINAL COMPLAINT AND ARREST WARRANT**

I, Paul S. Baumrind, depose and say:

I. INTRODUCTION

1. I am a Special Agent with the Federal Bureau of Investigation (FBI), and have been so employed since December 2004. I am currently assigned to the Boston Field Office in Boston, Massachusetts. Prior to joining the FBI, I was an Air Marshal of the Federal Air Marshal Service (FAMS). Prior to my employment with the FAMS, I was a police officer for the Baltimore County Police Department. I hold a Bachelor of Arts degree in Political Science and a Master of Science degree in Criminal Justice.

2. I am currently responsible for investigating healthcare fraud affecting both public and private insurers. I have participated in a variety of investigations, during the course of which I have interviewed witnesses, conducted physical surveillance, executed arrest and search warrants and reviewed various forms of evidence including email data, Medicare and Medicaid data, medical records, invoices, and business and bank records.

3. Through my training, education and experience, I am familiar with a variety of fraud schemes, including but not limited to, healthcare benefit programs. I have participated in numerous investigations related to health care fraud, the Food and Cosmetics Act and the Anti-Kickback statutes.

4. I have served as the affiant of over 10 state or federal search and seizure and/or arrest warrants. I have served as the affiant on at least three Title III (wiretap) affidavits.

5. This affidavit is in support of a criminal complaint charging Defendant **ELIZABETH**

P. GURRIERI, also known as “Elizabeth Wise,” (“**GURRIERI**”), born in 1975, and residing in Queen Creek, Arizona, together with others, with knowingly and intentionally conspiring to devise a scheme and artifice to defraud insurers and Pharmacy Benefit Managers to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises; and for the purpose of executing such scheme and artifice, to transmit and cause to be transmitted by means of wire, radio, or television communication in interstate and foreign commerce, writings, signs, signals, pictures, and sounds, to wit: facsimile transmissions and telephone calls, in violation of Title 18, United States Code, Sections 1343 and 1349. Examples of such calls include the following:

Patient	Date of call	Pharmacy Benefits Manager (PBM)
Patient 1	2/27/2014	PBM 1
Patient 2	2/27/2014	PBM 2
Patient 3	3/20/2014	PBM 1
Patient 4	4/2/2014	PBM 1
Patient 5	4/16/2015	PBM 1
Patient 6	2/17/2015	PBM 1
Patient 7	5/19/2015	PBM 1
Patient 8	8/23/2013	PBM 2
Patient 9	2/18/2014	PBM 1
Patient 10	1/6/2015	PBM 1

6. The information set forth in this affidavit results from, among other sources, interviews of witnesses, physical surveillance, and reviews of records, recorded telephone calls, and publicly-filed documents. The affidavit is based on my personal observations during the course of this investigation and on information conveyed to me by other government and law enforcement

officials. Because this affidavit is submitted for the sole purpose of seeking issuance of a criminal complaint, it does not include every fact known to me concerning the investigation. Instead, I only have included those facts that I believe are needed to establish the requisite probable cause to support the criminal complaint.

II. DISCUSSION OF EVIDENCE

Through knowledge gathered during this investigation, I know the following:

A. Pharma Company # 1 and the Fentanyl Spray.

7. Pharma Company # 1 is a Delaware corporation, a publicly traded entity, and the parent corporation in a corporate structure with multiple entities. The principal executive offices of Pharma Company #1 are located in Chandler, Arizona. Pharma Company #1 develops and sells in interstate commerce drugs intended for human use, including for sale and use in Massachusetts.

8. Opioids are a therapeutic class of drugs used to relieve pain. Fentanyl and analogues of fentanyl are among the most potent opioids available for human use. Fentanyl produces effects that are practically indistinguishable from the opioids morphine and heroin, but fentanyl has a greater potency and a shorter duration of action. Fentanyl is rapidly distributed to the brain, heart, lungs, kidneys and spleen.

9. At various times between March 2012 and October 2016, Pharma Company # 1 manufactured, marketed, and sold a fentanyl-based sublingual spray (the "Fentanyl Spray") in interstate commerce, including in the District of Massachusetts.

10. In or about 2011, Pharma Company # 1 submitted a new drug application to the Food

and Drug Administration (FDA), seeking approval to market the Fentanyl Spray. The FDA approved Fentanyl Spray in or about January 2012 for the management of breakthrough pain in patients with cancer, 18 years of age or older, who were already receiving and who were already tolerant to opioid therapy for their underlying persistent cancer pain.

11. The FDA determined that the Fentanyl Spray was a member of a category of drugs it called Transmucosal Immediate Release Fentanyl (TIRF) products. In addition to Fentanyl Spray, TIRF drugs included other fentanyl based rapid onset opioids.

B. Prior Authorization

12. The Fentanyl Spray, like other TIRF drugs, was expensive. Depending upon the dosage and prescribed units, a prescription for the Fentanyl Spray, costs hundreds, usually thousands, of dollars each month. For example, in or about May 2013, 30 sprays, called “units,” of 400 micrograms (mcg) of Subsys cost approximately \$1,170. Many practitioners wrote prescriptions for Subsys using 60 or even 120 units per month. In or about May 2013, 60 units of 400mcg of Subsys cost approximately \$2,340.

13. Many patients relied upon commercial insurance to subsidize the cost of taking the Fentanyl Spray. Publicly funded insurance also subsidized the costs of the Fentanyl Spray medication for their enrollees. For example, in or about May 2013 Pharma Company # 1 estimated that commercial insurance paid for approximately 87% of all Subsys prescriptions.

14. Many insurers controlled the costs of health care by managing the form and substance of care provided to their enrollees. Insurers often employed the services of organizations that specialized in managing the costs of prescription pharmaceuticals, called Pharmacy Benefit

Managers (PBMs). The costs of prescription drugs were controlled by insurers and PBMs using a number of restrictions including prior authorizations.

15. Almost all insurers required patients to obtain prior authorization before covering the cost of certain prescription drugs, including the Fentanyl spray and other TIRF medicines. The plan specific requirements of this form of managed care restriction varied depending upon the insurer and PBM. Many patients were required to have a specific medical diagnosis of cancer before authorization was granted. Most insurers and PBMs did not pay for an expensive drug until the patient had tried and failed certain other preferred medications.

16. Medical facilities, practitioners, insurers and PBMs, government entities, and pharmacies employed a set of codes to classify diseases and injuries. The codes, which were recognized around the world, were called the International Statistical Classification of Disease and Related Health Problems 9th Revisions (ICD-9). There was a recognized ICD-9 code for each medical diagnosis. Insurers and practitioners used ICD-9 codes when communicating about prior authorizations.

17. If prior authorization was granted, most, but not all, of the cost of the Fentanyl Spray was paid for by the insurer. Without prior authorization, the prescription was not filled unless the patient or a third party paid for the entire cost of drug.

C. The Reimbursement Center

18. Prescriptions for the Fentanyl Spray did not usually generate profits for Pharma Company # 1, unless insurers and PBMs authorized payment for the drug.

19. In or about October 2012, Pharma Company # 1 and others hired defendant

GURRIERI as a “prior authorization specialist.” In or about November 2012, Pharma Company # 1, **GURRIERI**, and others knew that that only approximately 30 to 33 percent of all prescriptions written for the Fentanyl Spray were receiving prior authorization. Pharma Company # 1, **GURRIERI**, and others began planning a program to increase the percentage of successful prior authorizations.

20. In or about January 2013 and continuing through in or about October 2016, Pharma Company # 1 operated and funded a unit dedicated to obtaining prior authorizations directly from insurers and PBMs (“the Reimbursement Unit”). When the Fentanyl Spray was prescribed, forms were sent to the Reimbursement Unit by facsimile and email purportedly from the office of the prescribing practitioner.

21. The form, called “Opt-Ins,” contained confidential patient information such as name and date of birth, insurer information, prescriber information, pharmacy information, the medical diagnosis or diagnoses for which the Fentanyl Spray had been prescribed, and the corresponding ICD-9 code associated with each diagnosis. Opt-In forms were used by employees at the Reimbursement Unit when communicating with insurers and PBMs. Opt-In forms were prepared at locations throughout the United States including from within the District of Massachusetts. Opt-Ins were sent via facsimile to the Reimbursement Unit in Arizona from locations throughout the United States including from within the District of Massachusetts. For example, one Sales Representative employed by Pharma Company # 1 took patient files to her home located in South Boston. From her home in Boston, the Sales representative filled out Opt-Ins and faxed them to the Reimbursement Unit in Arizona.

22. The Reimbursement Unit, in turn, became the entity that sought prior authorization

directly from the insurer and PBM.

23. **GURRIERI** was promoted to Manager of Reimbursement Services for Pharma Company # 1 in or about March of 2013. In or about the first week in April 2013, the Reimbursement Unit assigned a team of employees to call insurers and PBMs and verbally request prior authorizations. **GURRIERI** directly supervised that team of employees between in or about January 2013 through in or about July 2016.

D. Defrauding Insurers and PBMs

24. **GURRIERI** and other persons with leadership responsibilities over the unit held regular team meetings with Reimbursement Unit employees. The purpose of the meetings was to share best practices for obtaining authorizations from insurers and PBMs. Many of the best practices, were in fact fraudulent schemes. Reimbursement Unit employees were taught how to mislead and deceive insurers regarding their employment, patient diagnoses, and tried and failed medications. **GURRIERI** and others approved, fostered, and directed the use of these fraudulent schemes. In this environment, corruption became endemic within the Reimbursement Unit.

E. Reimbursement Schemes

25. During the course of this investigation, I have learned of numerous fraudulent schemes and artifices employed by **GURRIERI** in order to obtain payment authorization from insurers and PBMs. Examples of fraudulent schemes and artifices examples directed by **GURRIERI** and employed by others in order to obtain payment authorization from insurers and PBMs include, but re not limited to, the following:

Hiding the Reimbursement Unit

26. **GURRERI** and others knew that insurers and PBMs were often unwilling to engage a third party like the Reimbursement Unit in the prior authorization process and that if the insurers and PBMs knew that employees of Pharma Company # 1 were involved in the process, the ability of Pharma Company # 1 to ensure it received payment was diminished.

27. **GURRIERI** and others instructed unit employees to lead agents of insurers and PBMs to believe that they were calling from the office of the practitioner, as if they were employees of the practitioner.

28. **GURRIERI** and others at Pharma Company # 1 arranged for the Unit phone system to block access to the unit's number, so that agents of insurers and PBMs would not notice that the Unit employees were calling from an area code that was different than the area code of the prescribing practitioner. **GURRIERI** and others directed unit employees to not identify Pharma Company # 1 when answering the phone.

29. From in or about April of 2013 until in or about July 2016 agents of insurers and PBMs that directly interacted with the Reimbursement Unit were often fraudulently led to believe that the information necessary to making a prior authorization decision was supplied to them by office staff of the prescribing practitioner.

The Spiel

30. While practitioners acting in the usual course of professional practice possessed the authority to write a prescription for any legitimate medical purpose, **GURRIERI** and others knew that insurers and PBMs were less likely to authorize payment for a drug prescribed for a use that was not indicated on the drug's label.

31. Pharma Company # 1, **GURRIERI**, and others knew that the company would lose substantial profits if insurers and PBMs only authorized payment for the Fentanyl Spray when it was prescribed according to its label, for the management of breakthrough pain in patients with cancer, 18 years of age or older, who were already receiving and who were already tolerant to opioid therapy for their underlying persistent cancer pain.

32. When agents of insurers and PBMs asked if a patient was being treated for breakthrough cancer pain, Reimbursement Unit employees were directed by **GURRIERI** to answer using a script, sometimes called “the spiel.” The spiel intentionally misled agents of insurers and PBMs regarding their interaction with the prescriber. The “spiel” also deliberately omitted the word “cancer” in order to mislead agents of insurers and PBMs:

[R]esponse: ‘The physician is aware that the medication is intended for the management of breakthrough pain in cancer patients. The physician is treating the patient for their pain (or breakthrough pain, whichever is applicable).’

33. **GURRIERI** and others approved different versions of “the spiel.” Many insurers and PBMs recorded their prior authorization calls. Multiple Reimbursement Unit employees were recorded using the approved script to mislead insurers and PBMs.

Fake Diagnoses

34. Even with the identity of the Reimbursement Unit disguised, different insurers and PBMs reacted differently to prior authorization requests. For some insurers and PBMs, the misleading distinction between “breakthrough cancer pain” and “breakthrough pain” was enough to gain payment for the Fentanyl Spray. When agents of insurers and PBMs asked for

additional information, Unit employees, following the directions of their immediate supervisor **GURRIERI**, made additional misleading statements and misleading omissions to agents of insurers and PBMs in order to gain prior authorization:

a. **GURRIERI** and others knew that insurers and PBMs were more willing to grant prior authorization when a patient was diagnosed with dysphagia, or difficulty swallowing. **GURRIERI** and others instructed Reimbursement Unit employees to add the diagnosis of dysphagia when communicating with insurers and PBMs, regardless of whether the patient in fact had difficulty swallowing. Examples include:

-Former Reimbursement Unit employee # 1, who directly reported to **GURRIERI** between April 2013 and November 2014, stated that **GURRIERI** told her and other employees “put dysphagia on every single authorization.”

-Former Reimbursement Unit employee # 2, who directly reported to **GURRIERI** between April 2013 and May 2013, approached **GURRIERI** and asked her if a particular patient had difficulty swallowing. **GURRIERI** responded, “no, but we have to say that. That’s what we have to do to get it approved or else they won’t approve it.”

b. **GURRIERI** and others instructed Reimbursement Unit employees to review the medical history of patients in order to determine if the patient had ever been diagnosed with cancer. **GURRIERI** and others instructed Reimbursement Unit employees to tell insurers and PBMs that the current prescription was written to treat the previously diagnosed cancer, even when the patient had recovered or was in remission. **GURRIERI** and others directed Unit employees to falsely inform agents of insurers and PBMs that the Fentanyl Spray was prescribed to treat cancer pain despite knowing that the patient had recovered from cancer years before.

For example, Former Reimbursement Unit employee # 3 stated that **GURRIERI** told her that “if there was any history of cancer to give the breakthrough cancer pain code.” Former Reimbursement Unit employee # 3 stated that even if a patient had skin cancer 20 years ago, she was told to claim a diagnosis of skin cancer.

c. **GURRIERI** also instructed IRC employees to assert fraudulently a cancer diagnosis regardless of the patient’s history and regardless of whether the practitioner had prescribed Subsyst for a different diagnosis. For example, Former Reimbursement Unit employee # 4, who reported to **GURRIERI** between November 2013 and October 2014, stated that **GURRIERI** told her that, “Liz would come in and she'd be like, I got a chart and you know, I need you guys to do whatever you have to do. If you have to give them the cancer code, give it to them to get it approved, because it's a new script. Who wants it?”


Tried and Failed Medications

35. **GURRIERI** and others knew that insurers and PBMs often required patients to have tried and failed other drugs before granting a prior authorization. The medications required before authorization was granted varied among insurers and PBMs. **GURRIERI** and others tracked communication with agents of insurers and PBMs, acquiring the data necessary to assemble lists of tried and failed medications required for specific insurers and PBMs. **GURRIERI** and others used that information to instruct Reimbursement Unit employees regarding when and how to deceive insurers and PBMs. **GURRIERI** and others directed employees of the Reimbursement Unit to routinely falsely confirm lists of tried and failed medications to insurers and PBMs in order to obtain prior authorization for the Fentanyl Spray. For example, Former Reimbursement Unit Employee # 2 stated, “I would take the cheat sheet

drugs ..., I would take those medications and I would just add whatever else they did not step edit. ... So I would go down my ---my cheat sheet and see, okay, well, she didn't try this one, but I'm going to put that one on there. That's exactly how I was instructed by Liz [GURRIERI] to do so."

III. PROBABLE CAUSE

36. Based on the foregoing facts, and on my experience, training, and discussions with other individuals involved in this investigation, I believe that probable cause exists to conclude that **ELIZABETH P. GURRIERI**, also known as “Elizabeth Wise,” together with others, knowingly and intentionally conspired to devise a scheme and artifice to defraud insurers and PBMs to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises; and for the purpose of executing such scheme and artifice, to transmit and cause to be transmitted by means of wire, radio, or television communication in interstate and foreign commerce, writings, signs, signals, pictures, and sounds, to wit: facsimiles and telephone calls, in violation of Title 18, United States Code, Sections 1343 and 1349. Therefore, I request that a criminal complaint be issued charging that **ELIZABETH P. GURRIERI**, also known as “Elizabeth Wise,” accordingly, and that an arrest warrant be issued.



PAUL S. BAUMRIND
Special Agent
Federal Bureau of Investigation

Subscribed to and sworn before me on this 12th day of October, 2016.



Jennifer C. Boal
U.S. Chief Magistrate Judge for the District of
Massachusetts

